EXHIBIT M

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, CA

Appeal of:	**A. PROSSER**	OMHA Appeal No.:	**3-9079666355**
Beneficiary:	**A. PROSSER**	Medicare Part:	B
Medicare No.:	********1QM75**	Before:	**Adalberto Sardinas** Administrative Law Judge

DECISION

After considering the evidence and arguments presented in the record, I enter a **FULLY FAVORABLE** decision. The Appellant is entitled to Medicare payment for the Optune Tumor Treatment Field Therapy billed as electrical stimulation device used for cancer treatment (E0766) provided to the Appellant on May 16, 2019, June 16, 2019, July 16, 2019, and August 16, 2019. The issue of liability under Section 1879 of the Social Security Act is inapplicable because the decision is fully favorable to the Appellant.

PROCEDURALHISTORY

Novocure, Inc. (Novocure) submitted claims for Optune Tumor Treatment Field Therapy (Optune TTFT), billed as electrical stimulation device used for cancer treatment (E0766) and provided to the Appellant on May 16, 2019, June 16, 2019, July 16, 2019, and August 16, 2019. CGS, the Medicare DME Administrative Contractor denied the claim on initial determination. The Appellant appealed the denial and CGS issued an unfavorable redetermination decision.

The Appellant filed a reconsideration before Maximus Federal Services, the Qualified Independent Contractor (QIC). On January 21, 2020, the QIC issued an unfavorable decision denying the claims at issue on the basis that the submitted documentation did not support that the technology was efficacious and medically reasonable and necessary. (File 1).

The Appellant's timely filed request for Administrative Law Judge Hearing (ALJ) was received on January 29, 2020. The Appellant's request for hearing was timely filed. The amount in controversy meets the jurisdictional requirement. Accordingly, OMHA has jurisdiction to hear this appeal. Following review of the record, the undersigned finds that a favorable decision is warranted. Thus, the undersigned is issuing this decision based upon the evidence of record, without a hearing, as allowed under 42 CFR § 405.1038(a). All files were admitted into the record.

ISSUE(S)

The issue to be decided is whether under the provisions of Title XVIII of the Social Security Act (Act) and implementing regulations, Medicare reimbursement can be made for Optune TTFT, billed as electrical stimulation device used for cancer treatment (E0766) and provided to the Appellant on May 16, 2019, June 16, 2019, July 16, 2019, and August 16, 2019.

If it is determined that the services provided were not medically reasonable and necessary, whether payment should be made to the Provider by the Beneficiary or liability should be waived pursuant to Section 1879 of the Act.

APPLICABLE LAW AND POLICY

Section 1833(e) of the Social Security Act (Act) states that no payment shall be made to any provider of services unless supported by sufficient information. *See also* 42 C.F.R. § 424.5(a)(6).

Section 1862(a)(1) of the Act excludes from Medicare coverage and payment, items and services which are not medically reasonable and necessary for the diagnosis and treatment of an illness or injury, or to improve the functioning of a malformed body member. *See also* 42 C.F.R. § 411.15(k)(1).

Section 1879 of the Act provides that when Medicare excludes payment and coverage pursuant to Section 1862(a)(1) of the Act, payment may nevertheless be made for the items or services, if neither the beneficiary nor the provider knew, and could not reasonably have been expected to know, that payment would not be made for such items or services. *See also* 42 C.F.R. § 411.406.

Section 1869 (f)(2)(A) of the Act provides that review of any local coverage determination (LCD) shall be subject to the following limitations:

(i) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by an administrative law judge. The administrative law judge.—

> (I) shall review the record and shall permit discovery and the taking of evidence to evaluate the reasonableness of the determination, if the administrative law judge determines that the record is incomplete or lacks adequate information to support the validity of the determination;
> (II) may, as appropriate, consult with appropriate scientific and clinical experts; and
> (III) shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(ii) Upon the filing of a complaint by an aggrieved party, a decision of an administrative law judge under clause (i) shall be reviewed by the Departmental Appeals Board of the Department of Health and Human Services.
(iii) The Secretary shall implement a decision of the administrative law judge or the Departmental Appeals Board within 30 days of receipt of such decision.
(iv) A decision of the Departmental Appeals Board constitutes a final agency action and is subject to judicial review.

Only an aggrieved party may initiate a review of an LCD or provisions of an LCD by filing an acceptable complaint. 42 C.F.R. § 426.320.

Under 42 C.F.R. § 426.420(b), a contractor may revise an LCD under review to remove or amend the LCD provision listed in the complaint through the reconsideration process before the ALJ issues a decision regarding the LCD. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under 42 C.F.R. § 426.460(b). If an LCD is challenged and the ALJ presiding over that challenge finds that certain provisions in that LCD are not valid under the reasonableness standard, the claim submitted by the party challenging the LCD must be adjudicated without application of the invalid provisions of the LCD. *See* 42

C.F.R. § 426.460(b)(1)(i) and (iv). Additionally, if the LCD is revised, the revised LCD is applied to services that are performed after the effective date of the revised LCD. 42 C.F.R. § 426.460(b)(1)(ii).

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a national coverage determination (NCD), can establish or change a substantive legal standard governing the scope of the benefits or payment for services under the Medicare program unless promulgated as a regulation by CMS. NCDs promulgated by the Secretary of HHS under the authority of Section 1862(a)(1) of the Act dictate the criteria under which Medicare covers specified services, procedures or supplies. NCDs are binding upon ALJs. 42 C.F.R. § 405.1060(a)(4); *see* 42 C.F.R. § 405.1060(b)(1) ("An ALJ may not disregard, set aside or otherwise review an NCD").

Although not subject to the force and effect of law, CMS and its contractors issue policies, manuals and guidelines that describe criteria for coverage of selected types of medical items and services in the form of manuals and LCDs. 42 C.F.R. § 405.1062 states that an ALJ is not bound by LCDs or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. *Id.* An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect. *Id.*

Medicare Program Integrity Manual ("MPIM"), Pub. 100-08, Ch.13, Section 13.1.1 provides that an LCD, as defined in section 1869(f)(2)(B) of the Act, is a determination by a Medicare Administrative Contractor (MAC) respecting whether or not a particular item or service is covered on a contractor-wide basis in accordance with section 1862(a)(1)(A) of the Act. Section 1869(f)(2)(A) of the Act outlines the process for ALJ and Department of Appeals Board (DAB) review of LCDs. This process is known as the LCD Challenge Process. Procedures related to this challenge process are described in 42 C.F.R. § 426.

The LCD reconsideration process is a mechanism by which a beneficiary or stakeholder (including a medical professional society or physician) in the MAC's jurisdiction can request a revision to an LCD. MPIM, Pub. 100-08, Ch. 13, Section 13.3. The LCD reconsideration process differs from an initial request for an LCD in that it is available only for final effective LCDs. The whole LCD or any provision of the LCD may be reconsidered. In addition, MACs have the discretion to revise or retire their LCDs at any time on their own initiative.

In every proposed and final LCD, the MAC must summarize the evidence that supports coverage, limited coverage, maintenance of existing coverage in cases of LCD reconsideration or non-coverage. MPIM, Pub. 100-08, Ch. 13, Section 13.3.2. In conducting a review, MACs shall use the available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines. *Id.*

MPIM, Pub. 100-08, Ch. 13, Section 13.5.4 provides that an item or service may be covered by a contractor LCD if it is reasonable and necessary under 1862(a)(1)(A) of the Act. Under the MPIM, a service is reasonable and necessary when it is: (1) Safe and effective; (2) Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and (3) Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether

it is: (a) Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member; (b) Furnished in a setting appropriate to the patient's medical needs and condition; (c) Ordered and furnished by qualified personnel; (d) One that meets, but does not exceed, the patient's medical need; and (e) At least as beneficial as an existing and available medically appropriate alternative. *Id.*

LCD L34823, with a revision effective date of January 1, 2017, states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

Policy Article A52711 categorically places the TTFT device in the durable medical equipment category of Medicare-covered benefits. According to the Policy Article "[t]umor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6))." The Contractor provided the associated HCPCS code for the equipment and reported that the code (E0766) was in the frequent and substantial servicing payment category. *See* Policy Article A52711.

The proposed LCD L34823, with an effective date of September 1, 2019, provides as follows:

Tumor treatment field therapy (E0766) is only covered for the treatment of newly diagnosed glioblastoma multiforme (GBM) when all of the following criteria are met:

1. The beneficiary has histologically confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, supratentorial GBM; and,
2. The beneficiary has received initial treatment with maximal debulking surgery, followed by chemotherapy and radiotherapy; and,
3. Tumor treatment field therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy; and,
4. The beneficiary has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria; and,
5. The beneficiary has a Karnofsky Performance Score (KPS) of at least 70; and,
6. The beneficiary will use TTFT for at least 18 hours/day.

If all of the coverage criteria above are not met, claims for code E0766 will be denied as not reasonable and necessary.

Continued coverage of TTFT (E0766) beyond the first three months of therapy requires that no sooner than the 60th day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is continuing to use and is benefiting from TTFT.

Documentation of clinical benefit is demonstrated by:

1. Face-to-face clinical re-evaluation by the treating practitioner; and,
2. Objective evidence of adherence to the use of TTFT, reviewed by the treating practitioner.
3. Adherence to therapy is defined as the use of TTFT for at least 18 hours/day (see criterion 7 above).

If the above criteria are not met, continued coverage of TTFT will be denied as not reasonable and necessary.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary for the treatment of recurrent GBM.

The use of TTFT for any indications other than newly diagnosed GBM will be denied as not reasonable and necessary.

The Medicare Appeals Council ("Council") has, in many cases, addressed the issue of ALJs' authority to apply the doctrine of equitable estoppel. In the case of M.W.J. (Docket Number M-12-l086), the Council reviewed a case arising under Medicare Part D, wherein the ALJ applied the principles of equitable estoppel to allow a tiering exception based on the Part D plan's undisputed misrepresentations that the applicable copayment for a particular drug would be $45.00, instead of $385.55. In reversing the ALJ's decision, the Council noted that there was no legal basis for allowing a tiering exception, and that federal case law prohibits the application of equitable estoppel to require a government agency to allow a benefit that is not otherwise permitted by law. In the case of Y.B. (Docket Number M-18-3806), the Council reviewed another case arising under Part D, wherein the enrollee argued, on appeal, that the Part D plan should be estopped from denying his request for a tiering exception because it had allowed tiering exceptions (or overturned tiering exception denials) in similar circumstances, in the past. The Council rejected this argument, noting that the Medicare program "does not recognize or apply principles of equity or estoppel in adjudicating claims for Medicare reimbursement."

FINDINGS OF FACT AND ANALYSIS

At issue in this appeal is whether the TTFT (E0766) provided to the appellant on May 16, 2019, June 16, 2019, July 16, 2019, and August 16, 2019, is covered by Medicare. The QIC denied the instant claims on the basis that the submitted documentation did not support that the technology was efficacious and medically reasonable and necessary.

The Appellant's Position

The Appellant's legal representation, Ms. Debra M. Parrish, argues that the LCD relied on to deny coverage in the instant case has since been revised to allow coverage of TTFT for the treatment of newly diagnosed glioblastoma. Ms. Parrish notes that the evidence relied on by the contractor in issuing its new LCD predates the dates of service at issue. Ms. Parrish notes that Optune, the device that delivers TTFT, is FDA approved for recurrent and newly diagnosed glioblastoma. Ms. Parrish notes that the safety and efficacy of Optune have been demonstrated by numerous peer-reviewed studies published in some of the most prestigious journals, including the Journal of the American Medical Association (JAMA). Ms. Parrish notes that Optune is included in the National Comprehensive Cancer Network (NCNN) guidelines for recurrent and newly diagnosed glioblastoma. Thus, Ms. Parrish argues, the QIC's assertion that TTFT is without peer acknowledgement, is without basis. In response to the QIC's assertion that the studies supporting TTFT are biased, because they were supported by industry, Ms. Parrish asserts that most peer-reviewed studies have some form of industry sponsorship. Ms. Parrish asserts that TTFT has widespread adoption in the industry, noting that 59 of the 62 National Cancer Institute (NCI) designated cancer centers use the technology. In regards to this issue, Ms. Parrish also notes that virtually every major payor in the United States covers the technology. Ms. Parrish further notes that the technology has been assigned a HCPCS code, which she asserts demonstrates that the technology has been deemed safe and effective by the FDA, proven by studies to result in superior outcomes, is significantly different from already-coded durable medical equipment, and has achieved sufficient adoption by the relevant medical community to

justify the administrative burden of adding a new code. Ms. Parrish also requests that I disregard LCD L34823 on the basis of the appellant's limited treatment options, as well as the compelling support for the effectiveness of the technology as demonstrated by the studies, the opinions of professional societies, the FDA's approval, and other payors' policies. Finally, Ms. Parrish argues that the collateral estoppel doctrine bars the Secretary of HHS from re-litigating this controversy against the Appellant because two favorable decisions, which became final, were issued granting coverage for the TTFT provided to the Appellant. (File 8).

The Appellant's Medical Record

The Appellant, a 33-year old female, was diagnosed with glioblastoma multiforme in February 2016. She was status post gross resection and also chemo-radiation therapy. The Appellant's physician noted that she was a reasonable candidate for maintenance tumor-treating fields as per recent Phase III clinical trial results demonstrating overall survival benefit with following definitive surgery and chemo-radiation. The Appellant began her TTFT treatment. (File 8).

LCD Challenge and Revised LCD L34823

Prior to the issuance of the QIC's reconsideration an LCD challenge was filed by an "aggrieved party," a Medicare beneficiary who had a TTFT claim denied by a Medicare Administrative Contractor based on LCD L34823. The outcome of the LCD challenge is that on May 28, 2019, the ALJ who presided over the LCD challenge found that the LCD's record did not support the validity of LCD L34823 under the reasonableness standard. *Id.* Then, on July 18, 2019, the Medicare contractor issued a final decision revising LCD L34823 by extending Medicare coverage to use of TTFT services to treat newly diagnosed glioblastoma multiforme, effective September 1, 2019.

The revised LCD L34823, issued with an effective date of September 1, 2019 which permits coverage of TTFT for newly diagnosed glioblastoma, removes the applicability of the previous LCD as it pertains to newly diagnosed glioblastoma. If an LCD is challenged and the ALJ presiding over that challenge finds that certain provisions in that LCD are not valid under the reasonableness standard, the claim submitted by the party challenging the LCD must be adjudicated without application of the invalid provisions of the LCD. *See* 42 C.F.R. § 426.460(b)(1)(i) and (iv). Additionally, if the LCD is revised as in the case with LCD L34823, the revised LCD is applied to services that are performed after the effective date of the revised LCD. 42 C.F.R. § 426.460(b)(1)(ii).

Thus, by operation of law, the version of LCD L34823 that existed before September 1, 2019 is invalid and cannot be applied to the claims at issue in this appeal. Moreover, the revised version of LCD L34823 that became effective September 1, 2019 also cannot be applied to claims for dates of service before September 1, 2019. Therefore, both these versions of LCD L34823 cannot be applied to the claims at issue with dates of service of April 22, 2019, May 22, 2019, June 22, 2019, and July 22, 2019. These claims must be considered using Medicare's general coverage principles that rely on published peer-reviewed medical literature, the consensus of experts, and whether the treatment at issue has been accepted by the relevant medical community. *See* MPIM, Pub. 100-08, Ch. 13, Section 13.3.2.

The Disease and the Device

Gliobastoma is a primary malignancy of the brain, a highly aggressive brain tumor frequently striking men and women at the peak of life, and the most prevalent primary malignant brain

tumor in adults. At the end of 2015, the Journal of the American Medical Association (JAMA) reported that "[p]rognosis remains poor with no major treatment advance in more than a decade." With optimal treatment, the median survival of individuals diagnosed with glioblastoma is 15 months from diagnosis. Standard treatment options include resection, chemotherapy, and radiation therapy. Within 9 months of initial treatment, most tumors recur. Treatment options after recurrence are generally limited and include repeat resection with possible implantation of carmustine wafers, additional radiation therapy, and chemotherapy.

Optune is a portable battery or power operated device which produces alternating electrical fields (TTFT) within the human body. The TTFT disrupts the rapid cell division exhibited by cancer cells. Four adhesive patches, or transducer arrays, are applied to the scalp and connected to the device to deliver the therapy. According to the Provider's Product Dossier for Optune, the treatment is intended for adult patients who are 22 years of age or older with histologically-confirmed glioblastoma multiforme. For adult patients with newly-diagnosed, supratentorial glioblastoma, Optune coupled with temozolomide is indicated following maximal debulking surgery and completion of radiation therapy along with standard of care chemotherapy. For recurrent glioblastoma, Optune is intended to be used as a monotherapy and as an alternative to standard medical therapy for glioblastoma after surgical and radiation options have been exhausted.

Optune, previously called NovoTTF-100A System, received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the Provider received premarket approval from the FDA for use of Optune in patients newly diagnosed with glioblastoma.

(Multiple Files).

Published Medical Studies

On December 15, 2015, JAMA published an interim analysis of the results of this phase III clinical trial related to TTFT. (Roger Stupp, M.D., et al., *Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial*, 314 JAMA 2535-43 (Dec. 15, 2015) The analysis of the clinical trial concluded that adding TTFT to maintenance temozolomide chemotherapy in a population with new onset glioblastoma "significantly prolonged progression-free and overall survival." After the study concluded, the patients in the control group with ongoing maintenance therapy were offered TTFT therapy. Thirty-five of those patients chose to receive TTFT therapy. A final analysis of the randomized phase III clinical trial in December 2017 concluded that "the addition of TTFields to maintenance temozolomide chemotherapy vs maintenance temozolomide alone, resulted in statistically significant improvement in progression-free survival and overall survival." (Optune Peer-Reviewed Literature – Ruger Stupp, M.D., et al., *Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients With Glioblastoma: A Randomized Clinical Trial*, 318 JAMA 2306, 2315 (Dec. 19, 2017).

The NCCN included alternating electric field therapy for glioblastoma in its NCCN Clinical Practice Guidelines in Oncology for Central Nervous System Cancers (version 1.2016). Use of alternating electric field therapy for recurrent glioblastoma was given a 2B rating, meaning that "[b]ased upon lower-level evidence, there is NCCN consensus that the intervention is appropriate." (*See* NCCN, *NCCN Categories of Evidence and Consensus* (hereinafter, NCCN Categories),

https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx). By the time of its 2018 updates to these guidelines, the NCCN had increased its rating for alternating electric field therapy (used in conjunction with standard RT and concurrent temozolomide and adjuvant temozolomide) to category 1, the NCCN's highest rating, meaning that "[b]ased upon high-level evidence there is uniform NCCN consensus that the intervention is appropriate." https://www.nccn.org/about/news/ebulletin/ebulletindetail.aspx?ebulletinid=1370

(Multiple Files).

TTFT is Medically Reasonable and Necessary

The MPIM instructs contractors to consider a service to be reasonable and necessary where that service is: (1) safe and effective; (2) not experimental or investigational; and (3) appropriate (taking into account whether the service (a) is furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition, (b) is furnished in an appropriate setting, (c) ordered and furnished by qualified personnel, (d) meets, but does not exceed, the patient's medical need, and (e) is at least as beneficial as an existing and available medically appropriate alternative. MPIM, Pub. 100-08, Ch. 13, Section 13.5.4.

Safe and Effective Therapy

Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1).

The Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients (like the Appellant) with newly diagnosed glioblastoma. While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use in patients with both recurrent and newly diagnosed glioblastoma. This is wholly consistent with Medicare requirements. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence. This also shows that the device is not experimental or investigational.

The FDA's conclusion has been fortified by medical investigation in the years that followed premarket approval. During that time, clinical studies evaluating the use and efficacy of the Optune device have resoundingly concluded that the device is safe and effective. The Appellant submitted various records of supporting medical literature, including articles and studies, which demonstrate the safety and efficacy of TTFT for glioblastoma. Results from a phase III clinical trial utilizing TTFT in patients with newly diagnosed glioblastoma showed that the addition of TTFT to maintenance temozolomide chemotherapy "significantly prolonged progression-free and overall survival."

(Multiple Files).

Not Experimental or Investigational

The use of TTFT is generally accepted by the medical community. In the 2016 version of the NCCN Clinical Practice Guidelines in Oncology for Central Nervous System Cancers, alternating electric field therapy is an option categorized as 2B for treatment of glioblastoma. The NCCN has since upgraded its rating of alternating electric field therapy (in combination with chemotherapy and radiation) to category 1. This recognition of uniform consensus based on the highest-level evidence is the NCCN's gold standard and supports coverage using the highest level of evidence possible. Moreover, this rating is embodied in treatment guidelines from a renowned national cancer organization (as opposed to evidence based on an individual physician treating a single patient in a clinical setting) and, as such, is particularly persuasive and authoritative. It provides convincing evidence that TTFT treatment is accepted in the medical community as not experimental or investigational.

TTFT is Appropriate for the Appellant

Finally, it is necessary to evaluate the extent to which the TTFT device was appropriate for the Appellant and her care. Applying the considerations mandated by the MPIM, the record in this case convincingly demonstrates that it was.

Based on the arguments and evidence presented, I decline to apply the current LCD because the policy is not applicable to the appeal at issue. I find that the Appellant has submitted ample evidence to support a favorable decision in this appeal based on the peer-reviewed literature, FDA approval, and overwhelming current acceptance in the medical community for the Optune system as a treatment option for recurrent and newly diagnosed glioblastoma. With use of TTFT, the data and medical consensus shows that the Appellant would be provided a greater quality of life as well as increased survival rate.

In this case, given the aggressive nature of the GBM tumor, it appears from all the literature that TTFT is the Appellant's most promising FDA-approved treatment option available to her and that this treatment option has been widely accepted as the standard of treatment in patients with recurrent and newly diagnosed GBM.

It should be noted that the final revised LCD now allows payment for newly diagnosed glioblastoma, effective September 1, 2019. Although the revised LCD does not apply to the services at issue because of the dates of service in this case are prior to the effective date of September 1, 2019 and applies to newly diagnosed glioblastomas, the revised LCD is indicative of the persuasiveness of the peer-reviewed literature and current acceptance for this device in the medical community for both newly diagnosed and recurrent glioblastomas.

Accordingly, coverage of TTFT treatments prior to September 1, 2019 should be based on the peer review literature and not on the prior LCD, in accordance with 42 C.F.R. 426.420. For the reasons stated, I find that TTFT through the Optune device is a covered treatment that is safe and effective based on the multiple peer-reviewed publications. TTFT was properly ordered by the Appellant's treating physician in accordance with accepted standards of medical practice for treatment of the Appellant's glioblastoma. For all of the foregoing reasons, I conclude that the TTFT device known as Optune has been shown to be safe and effective and is medically reasonable and necessary for the treatment of the Appellant's condition.

Based on the foregoing, I find that the Appellant is entitled to Medicare payment for the services at issue. As this decision is fully favorable to the Appellant, the issue of liability under Section 1879 of the Act is inapplicable.

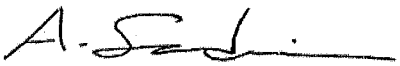
CONCLUSIONS OF LAW

It is my decision, based on applicable laws, regulations and CMS guidance, that the Appellant is entitled to Medicare payment for the Optune Tumor Treatment Field Therapy (Optune TTFT), billed as electrical stimulation device used for cancer treatment (E0766) and provided to the Appellant on May 16, 2019, June 16, 2019, July 16, 2019, and August 16, 2019. As this decision is fully favorable to the Appellant, the issue of liability under Section 1879 of the Act is inapplicable.

ORDER

For the reasons discussed above, this decision is **FULLY FAVORABLE**. The Medicare Administrative Contractor is ordered to process the claim in accordance with this decision.

SO ORDERED



Adalberto Sardinas
Administrative Law Judge